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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,395	06/08/2001	David K. Gardner	033948-0102	7684

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

17

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,395

Applicant(s)

GARDNER ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 and 30-33 is/are allowed.
- 6) ☒ Claim(s) 10 and 26-29 is/are rejected.
- 7) ☒ Claim(s) 11-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Action is in response to the communication filed on 4/22/03, as Paper No. 15. The amendment filed 4/22/03 has been entered. Claims 17-20 have been cancelled. Claims 1, 10, 26, 30 and 33 have been amended. Claims 1-16 and 21-34 are presently pending in the application and are addressed herein.
2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Election/Restrictions

3. Claims 21-25 and 34 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim for the reasons of record. Election was made **without** traverse in Paper No. 7, filed 5/2/02.
4. Claims 1-16 and 26-33 are examined herein.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 4/22/03 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112, second paragraph

6. The rejection of claims 6, 10-20 and 26-3 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of the claim amendments and cancellation of claim 17.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1-6, 10-20 and 30-33 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,153,582 (Skelnick) in view of U.S. Patent No. 5,612,198 (Becquart) and an article by Kjems has been withdrawn.

8. The declaration under 37 CFR 1.132 filed 4/22/03 is sufficient to overcome the rejection of claims based upon US Patent No. 6,153,582 (Skelnick).

9. The Applicants have submitted the declaration of David K. Gardner which provides experimental data demonstrating that embryos cultured in the medium taught by Skelnick failed to survive past a 1-cell stage. Therefore, Skelnick does not teach a medium that increases the viability of gametes or embryos. Furthermore, Applicants have submitted several references which indicate that at the time of filing one of ordinary skill in the art would not reasonably have expected to produce a culture medium which increases the viability of gametes or embryos by replacing serum derived-albumin with recombinantly produced human albumin. In addition to the newly submitted references, the Examiner also acknowledges that the Keenan article (Cytotechnology 1997; cited in a previous IDS) also supports the argument that one of skill in the art would not expect recombinant human albumin (free of all serum elements) would support

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cell growth or increase cell viability. Therefore, the arguments/declaration presented are persuasive and the rejection is withdrawn.

10. The rejection of claims 1-20 and 30-33 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,140,121 (Ellington) in view of U.S. Patent No. 5,612,198 (Becquart), an article by Kjems and Skelnick has been withdrawn.

11. Applicants have submitted several references which indicate that at the time of filing one of ordinary skill in the art would not reasonably have expected to produce a culture medium which increases the viability of gametes or embryos by replacing serum derived-albumin with recombinantly produced human albumin. In addition to the newly submitted references, the Examiner also acknowledges that the Keenan article (Cytotechnology 1997; cited in a previous IDS) also supports the argument that one of skill in the art would not expect recombinant human albumin (free of all serum elements) would support cell growth or increase cell viability. Therefore, the arguments presented are persuasive and the rejection is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claims 10 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent No. EP 0 947 581 A1 (Amatsuji et al.; cited in a previous IDS)

14. Claim 10 is drawn to a mammalian culture medium comprising recombinant human albumin and a medium that can support cell development wherein the mammalian culture medium increases the viability of gametes or embryonic cells cultured in the medium and further wherein the culture medium is free from non-recombinant human albumin. Claims 26-29 are drawn to a kit comprising (a) a medium comprising recombinant human albumin and (b) instructions for the use of the kit (claim 26); wherein the kit is free of one or more non-recombinant macromolecules, non-recombinant human albumin, or non-fermented hyaluronan (claim 27); where the instructions provide how to make a mammalian culture medium (claims 28 and 29).

15. It is respectfully pointed out that a composition and said composition in a kit are not considered patentably distinct. Therefore, any rejection that applies to the composition also is appropriately applied to the composition in a kit. Furthermore, instructions providing how to use the composition carry no patentable weight because the instructions merely indicate intended uses for the composition. Therefore, any rejection that applies to the composition also is appropriately applied to the composition in a kit with instructions on how to use the composition.

16. Amatsuji teaches a serum-free mammalian culture medium containing recombinant human albumin and is free of non-recombinant human albumin (e.g., see abstract; p. 2 first column; p. 2, second column, etc.). As mentioned above, a composition and said composition in a kit are not considered patentably distinct and instructions providing how to use the composition carry no patentable weight because the instructions merely indicate intended uses for the

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composition. Therefore, the rejection of the composition (the medium comprising recombinant human albumin and free of non-recombinant albumin; i.e., claim 10) is also appropriate for the kit comprising the composition and the kit comprising the composition and instructions on how to use the composition (claims 26-29).

Allowable Subject Matter

17. Claims 1-9 and 30-33 are allowed, considering that one of ordinary skill in the art would not have expected recombinant human albumin to support cell growth and increase gamete or embryo viability based on the teachings in the art at the time of filing.

Claim Objections

18. Claims 11-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DAVE T. NGUYEN
PRIMARY EXAMINER

J. Eric Angell
June 26, 2003